Specialty Pharmacy Trends And Plan Sponsor Value

Current benefit designs can't handle the increasing use and cost of biologic therapies. New tactical strategies to forge value-based insurance are needed now.

BY F. RANDY VOGENBERG, RPh, PhD

The therapeutic paradigm is shifting toward early, and longer, disease treatment. For many new drug technologies (NDTs) — biologics and their corresponding dose form or drug delivery technology — the value of dose escalation has buttressed the utilization of specialty pharmacy products.

Specialty pharmacy spending has been considered a high-cost, low-occurrence event for plan sponsors, which include employers, unions, and other group buyers of health insurance and pharmacy benefit coverage. The specialty drug category includes the biologics and other injectable and high-cost pharmaceuticals that require special preparation, handling, and monitoring. These medications may be administered either by a physician or the patient. The Centers for Medicare & Medicaid Services (CMS) defines specialty drugs as medications that cost more than $500 for a one-month supply. Recently, the specialty drug category has expanded to include oral medications that fit CMS' definition, primarily oral oncologics and drugs with alternative or new delivery systems.

One example of the expanding use of specialty drugs is the treatment of rheumatoid arthritis (RA), which has seen a shift toward early treatment with biologics to prevent irreversible joint damage (Doan 2006). The less expensive disease-modifying antirheumatic drugs (DMARDs) are now being used in conjunction with biologics as part of long-term treatment plans for RA. Widely used RA products, such as

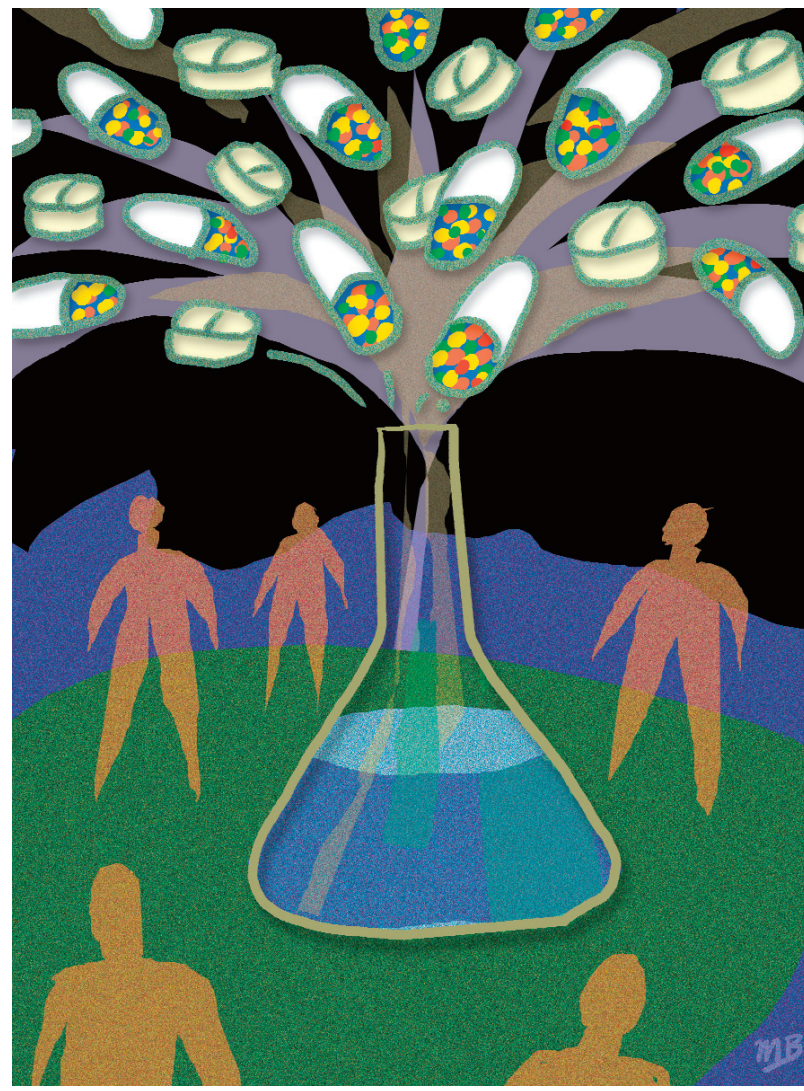

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TABLE
Selected specialty drugs in development or FDA approved, 2009–2011

Brand name	Generic name	Route of administration	Indication	Expected release date
Cimzia	certolizumab	subcutaneous	Crohn's disease rheumatoid arthritis	2008* 2009*
Feraheme	ferumoxytol	infusion	anemia	2009*
Atryn	recombinant antithrombin III	infusion	anticoagulant	2009*
Simponi	golimumab	subcutaneous	rheumatoid arthritis ankylosing spondylitis psoriatic arthritis	2009*
Benlysta	belimumab	infusion	lupus rheumatoid arthritis	2009
Actemra	tocilizumab	infusion	rheumatoid arthritis	2009
Stelara	ustekinumab	subcutaneous	psoriasis	2009
Xarelto	rivaroxaban	oral	anticoagulant	2009
Fampridine-SR	fampridine 4-aminopyridine sustained-release	oral	multiple sclerosis	2009
Mylinax	cladribine	oral	multiple sclerosis	2010
	fingolimod	oral	multiple sclerosis	2010
	phenoxodiol	oral	prostate cancer	2010
Panaclar	BG-12 dimethyl fumarate	oral	multiple sclerosis	2010
Onconase	ranpirnase	infusion	mesothelioma	2010
	tesamorelin (TH-9507)	subcutaneous	HIV-related lipodystrophy	2010
	ALTU-238	subcutaneous	growth hormone deficiency	2010
	idraparinux	subcutaneous	anticoagulant	2010
Albuferon	albumin interferon alpha 2b	subcutaneous	Hepatitis C	2010
	boceprevir	oral	Hepatitis C	2010
	celgosivir	oral	Hepatitis C	2010
	telaprevir	oral	Hepatitis C	2011

* FDA approved as of Aug. 21, 2009. Certolizumab indications shown by year of approval.
Sources: 2008 Express Scripts Drug Trend Report, company news releases

adalimumab (Humira), etanercept (Enbrel), and infliximab (Remicade) are being joined on the market by certolizumab (Cimzia) and golimumab (Simponi), which have a mechanism of action similar to the three established biologics. And soon, the U.S. Food and Drug Administration is expected to approve ocrelizumab and ofatumumab, which have a unique mechanism of action to treat RA (Medco 2008). It is not clear yet how these drugs will fit into the RA treatment paradigm.

As new treatment modalities are more widely used for treating chronic conditions, plan sponsors will be challenged to manage the rising cost and increased utilization of specialty drugs and NDTs.

MORE DRUGS, MORE UTILIZATION

The specialty drug pipeline includes 633 biologics currently in development (PhRMA 2008). Specialty drugs that have been recently approved or may be approved by the U.S. Food and Drug Administration over the next four years are listed in the Table. It is important to focus on new medications that may potentially have high utilization, as this will drive the specialty drug trend. Those conditions with large populations representing potentially higher utilization of specialty drugs are highlighted in red in the Table, and include drugs for prostate cancer, anemia, and anticoagulants. Oral medications, in green, will also contribute to growth in specialty trend.

DRIVING QUALITY IN THE VALUE EQUATION

Because the denominator of cost is so high, plan sponsors must start thinking differently about coverage and come up with new ways of assessing value to reap the most benefit from the NDTs and other expensive specialty drugs. Assessing value requires an assessment of both the finance and access components to determine the relationship of cost reimbursement to access. One of the major challenges plan sponsors face is that traditional coverage reimbursement mechanisms, such as copayments and coinsurance, do not adequately lessen the cost burden of NDTs — and could be prohibitively expensive for many, if not most, patients who need the medications. To get the most value from a therapy, plan sponsors should focus first on ensuring that patients are being appropriately selected for treatment. Value has been traditionally defined as quality over cost. Value propositions should, then, focus effectiveness and affordability in measurable terms.

Assessing value is a big challenge for plan sponsors. Randomized controlled trials are the Holy Grail for the scientific world, but they do not include the direct and indirect costs of treatment as part of their analyses. Smaller studies tailored to employers and insurers are more applicable for employers but lack scientific rigor. Additionally, it is difficult to determine the cost savings from reduced hospitalizations and fewer medical visits as well as the indirect employer costs, because specialty pharmacy is administered both on the medical and pharmacy benefit side. What is needed, then, is a total cost-of-care model that integrates cost and outcome data from the medical and pharmacy services.

To successfully manage the demand for NDTs and specialty drugs and their increasing costs, plan sponsors must be proactive and innovative. Successful management requires coordination with drug companies and specialty pharmacy providers to increase adherence and to provide performance-related information. One way to do this is for plan sponsors to develop a drug management program so they can choose the specialty pharmacy program with the best adherence data. These programs will introduce competition among specialty pharmacy providers into the market, which, in turn, will increase the value of the specialty drug to both the patient and the plan sponsor. Many specialty pharmacies have already created such programs (Express Scripts 2008, Medco 2008). Also, to determine value, specialty pharmacy programs can provide measurable patient outcome data that can be used to determine the quality of care patients are receiving. Those specialty pharmacy programs that provide the most compelling outcomes data will be adopted, and the continuous improvement of comprehensive specialty pharmacy programs will help drive quality in the value equation.

BEATING CULTURAL LAG

Cultural lag theory dictates that a new technology will advance faster than clinical guidelines regarding how and when to use the new technology (Skiba 2007). Applied to NDTs, this lag gives plan sponsors time to develop an effective benefit design before the NDT becomes highly utilized. However, if plan sponsors fail to take advantage of this lag, it will ultimately lead to a benefit design that fails to meet the needs of its customers. Plan sponsors must anticipate changes before new NDTs and new indications are approved for market. In this context, sponsors must first address finance and access for these drugs, then address the inadequacy of current benefit designs and consider new insurance underwriting and finance strategies that acknowledge the economic costs associated with NDTs. Value-based insurance designs are one option that could improve access and finance issues once a strategy is developed. New value-based health plan programs for NDTs will give plan sponsors a model for future health benefits programs.

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Disclosure

F. Randy Vogenberg, RPh, PhD reports that he has no affiliations that may constitute a conflict of interest with respect to companies or products mentioned in this article.

Acknowledgement:

The author acknowledges the editorial and reference research assistance by Sara Brescia, Doctor of Pharmacy candidate, University of Rhode Island College of Pharmacy.